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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/535,253      | 02/09/2006  | Nagarajan Kuppuswamy | 033899-0113         | 5990             |

22428 7590 01/09/2008  
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| EXAMINER |
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CHO, JENNIFER Y

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| ART UNIT | PAPER NUMBER |
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1621

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| MAIL DATE | DELIVERY MODE |
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01/09/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/535,253 | <b>Applicant(s)</b><br>KUPPUSWAMY ET AL. |  |
|                              | <b>Examiner</b><br>Jennifer Y. Cho   | <b>Art Unit</b><br>1621                  |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **Detailed Action**

Receipt is acknowledged of the Response filed 10/15/2007.

Claims 1-20 are considered to be the elected invention. Claims 13-20 have been newly added.

Applicant's amendment filed 10/15/07 is sufficient to overcome the objections of the previous office action. Therefore, the objections have been withdrawn.

### **Claim Rejections – 35 USC 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Peverali et al. (US 6,518,456), in view of Cannata et al. (US Patent Publication 2004/0068011), for the reasons of record as set forth in the previous office action. Amended claims 10-12 and newly added claims 13-20 are rejected over Peverali et al. (US 6,518,456), in view of Cannata et al. (US Patent Publication 2004/0068011), for the same reasons as in the previous office action.

### Response to Arguments

Applicant's arguments have been considered but are not persuasive for the following reasons:

The Examiner acknowledges Applicant's argument that "gabapentin hydrochloride and the gabapentin hydrochloride hemihydrate are certainly not one and the same".

The Examiner agrees that the gabapentin hydrochloride hemihydrate form is different from gabapentin hydrochloride because of the water solvation in the **solid form**. The formation and interconversion of gabapentin hydrochloride to gabapentin hydrochloride hemihydrate is dependent on the water activity of the recrystallization solvent. Note that Peverali et al. states the hemihydrate hydrochloride is obtained after drying, as a **solid** (column 2 lines 28-29). However, applicant's claims are drawn to an **aqueous solution** of gabapentin hydrochloride. The examiner asserts that once gabapentin hydrochloride hemihydrate is dissolved in a water solution (with no solvent present) it is effectively an aqueous solution of gabapentin hydrochloride. Thus, the art reads on applicant's claims, as stated in claim 1, "preparing an aqueous solution of gabapentin hydrochloride in water". In addition, Peverali et al. substantiates this by teaching that "gabapentin is obtained by treating a hot concentrated aqueous solution of **gabapentin hydrochloride** with sodium hydroxide to the amino acid isoelectric point..." (column 2, lines 30-32).

Furthermore, Peverali starts with applicant's gabapentin hydrochloride and forms pure gabapentin. Applicant's claims include the word "comprising", which allows for

additional steps in the process. The claimed invention allows for ethanol recrystallization to form the gabapentin hydrochloride hemihydrate. Thus the claims read on a process to form the hemihydrate in the synthesis of gabapentin from gabapentin hydrochloride.

The Examiner acknowledges Applicant's argument for "surprising and unexpected benefits of Applicant's process resulting in low chloride and/or low lactam content."

The Examiner has examined Applicant's Summary Table 1 reciting low values for the chloride and lactam. However, the Examiner points to Peverali et al. isolated gabapentin in which the chloride content was 0.007%, corresponding to 42 ppm (column 6, line 46) and since the HPLC purity of gabapentin was 100%, the lactam concentration is assumed to be lower than detectable. Thus the Examiner does not agree that the Applicant has shown "surprising and unexpected benefits of Applicant's process resulting in low chloride and/or low lactam content.", in comparison to the prior art.

The Examiner acknowledges Applicant's argument that Cannata et al. "does not disclose, teach or suggest a solvent system of IPA, methanol and water".

In response, the Examiner points to Cannata et al. which explicitly teaches the use of methanol and isopropyl alcohol in the recrystallization method (page 2, section 28). In addition, it is reasonable to expect that water would be present in the alcohol solutions, particularly since Cannata does not explicitly state the solvents are anhydrous. Thus the art reads on applicant's claims.

The Examiner acknowledges Applicant's argument that there is no motivation to combine the two references because Peverali et al. does not require an ion exchange resin and Cannata et al. does teach an ion exchange conversion process.

In response to Applicant's argument that there is no suggestion to combine the references, the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it is permissible for the Examiner to rely on disclosures, which fairly teach embodiments of Applicant's invention. The claims require a multitude of elements and it is reasonable for one of ordinary skill in the art to consider these elements being used together. Furthermore, though Peverali et al. and Cannata et al. may differ on the use of an ion exchange resin, they both teach conversion of gabapentin hydrochloride to form pure gabapentin. Thus one of ordinary skill in the art would be motivated to combine the references, particularly in regard to recrystallization solvents, which are not involved in the ion exchange resin step.

Therefore, it would be prima facie obvious to one of ordinary skill in the art at the time of the invention, to use the teachings of Cannata et al., particularly in regard to the purification and recrystallization of gabapentin, for Peverali et al.'s production of gabapentin, since it is well-known that a variety of purification and recrystallization

methods can be used in the conversion of gabapentin hydrochloride to gabapentin. Absent any showing of unusual and/or unexpected results over applicant's particular limitations, the art obtains the same effect on the purity of gabapentin. Furthermore, the limitations in some of the dependent claims, not expressly taught in the art, are also deemed to be obvious. One of ordinary skill in the art would be motivated to make fine adjustments and optimize these parameters to arrive at the instantly claimed invention. The expected result would be an improved process for the preparation of gabapentin with high purity.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Y. Cho whose telephone number is (571) 272 6246. The examiner can normally be reached on 9 AM - 6 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 272 0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Cho  
Patent Examiner  
Art Unit: 1621



FOR

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Yvonne Eyler  
Supervisory Patent Examiner  
Technology Center 1600